

Att'y Dkt. No.: US-111

U.S. App. No: 10/673,860

REMARKS

Favorable reconsideration, reexamination, and allowance of the present patent application are respectfully requested in view of the following remarks.

Rejection under 35 U.S.C. § 112, first paragraph

In the Office Action, beginning at page 2, Claims 1, 3, 4, 7, 8, 10, and 11 were rejected under 35 U.S.C. § 112, first paragraph, as reciting subject matters that allegedly fail to comply with the written description. Applicant respectfully requests reconsideration of this rejection.

First, the Office Action states on page 6 that "the claims as drafted encompass any mutant of the AJ12036 strain." However, this is simply not true. That is, the claims encompass methods using the AJ12036 strain, and mutants thereof, wherein the bacterium (either the AJ12036 or mutants thereof) is able to secrete heterologous protein at least 2 fold higher than ATCC13869 which also contains the genetic construct. In other words, not every mutant of strain AJ12036 is encompassed, but only those which retain the activity of being able to secrete heterologous proteins at the stated amount. The AJ12036 strain has this activity, and the claims encompass AJ12036-derived strains which have retained this activity, but otherwise might not be identical, i.e. mutants. The Office Action seems to imply that the person of skill in the art must be able to produce *de novo* mutants having the increased secretory production of proteins. However, since the mutant of the present invention is an AJ12036-derived mutant, i.e. AJ12036 is the starting material or parent strain, one of skill in the art does not need to be able to generate ANY mutant which has the recited activity based upon the description in the specification, but merely must be able to recognize mutants derived from AJ12036 which have retained said activity. Clearly, making such a determination is described in the specification and is within the skill of the ordinarily-skilled art worker.

The Office Action states that page 3, lines 14-17 of the specification discloses that

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mutants may include any strains obtained by mutagenesis and selection procedures for increased secretory properties. This seems to be referring to the last sentence of column [0026] in page 10; however, this section merely describes the generation of a mutant similar to AJ12036 from -strains which do not have such a high secretion capacity, for example from the wild-type strain, that is, the *de novo* generation of a mutant having an increased capacity of secretory production of proteins at least 2-fold higher than the wild-type when the same genetic construct is introduced to them. Since the "mutant" referred to in Claim 1 is derived from an AJ12036 strain (the parent strain) which has the capacity of secreting proteins at least 2-fold higher than the wild-type, the "selection procedures" referred to by the Office Action will not be required to the extent that the Office Action points out.

Again, the Applicant respectfully notes that recitation of "a mutant thereof" means a mutant which is obtained from AJ12036, using AJ12036 as the parent strain (a starting material). Namely, this recitation does not intend to encompass a mutant from a strain which does not have high secretion capacity, for example, from the wild-type strain. Although such mutants obtained from AJ12036 may be tested for the high capacity of secretory production, such a test will merely be a confirmation of the capacity to assure that high secretory production capacity of the parent strain (AJ12036) has not been lost.

The Office Action further points out on page 4, lines 10-13 that while the specification provides broad guidance on methods of mutagenesis and selection which may be used to isolate mutant bacteria, there is no disclosure of the precise mutation of the AJ12036 coryneform bacteria useful for obtaining and/or maintaining the recited increased secretion properties. Since the mutant strains as claimed are limited to AJ12036 and a mutant thereof, which already has the desired activity, it is not necessary to specify mutations which will impart such activity to the AJ12036 mutants.

The Applicant believes that a mutant derived from AJ12036 will not lose the

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activity of being able to highly secrete heterologous proteins. Namely, a mutant which is derived from AJ12036 will also have the ability to secrete a heterologous protein at least 2-fold higher than the wild-type. This is because a random mutation would rarely introduce a mutation in the region responsible to this secretion capacity. For example, the mutation that caused the defect of producing a cell surface protein did not affect this high secretory production capacity, which is demonstrated in Example 9 in the specification.

For at least the foregoing reasons, Applicant respectfully submits that Claims 1, 3, 4, 7, 8, 10 and 11 fully comply with 35 U.S.C. § 112, first paragraph, and therefore respectfully requests withdrawal of the rejection thereof under 35 U.S.C. § 112.

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Conclusion

For at least the foregoing reasons, Applicant respectfully submits that the present patent application is in condition for allowance. An early indication of the allowability of the present patent application is therefore respectfully solicited.

If Examiner Vogel believes that a telephone conference with the undersigned would expedite passage of the present patent application to issue, he is invited to call on the number below.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and the undersigned authorizes such fees be charged to our deposit account 50-2821.

Respectfully submitted,

By: _____


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